IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/840,197

Confirmation No.: 7233

Filing Date: May 6, 2004

Examiner: Karlheinz R, Skowronek

Group Art Unit: 1631

Applicants: Christopher J. Godfrey et al.

For: METHODS FOR DETERMINING OPTIMAL DOSES FOR

A FIRST INVESTIGATIONAL ADMINISTRATRION IN

HUMANS

September 10, 2007 Cambridge, Massachusetts

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

AMENDMENT AND REPLY TO OFFICE ACTION

Sir:

This is in response to the March 9, 2007 Office Action in the above-identified application. With a five-month extension of time, a reply is due September 10, 2007. Consequently, this reply is timely submitted.

Remarks begin at page 2 of this Reply.